UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., No. 07-CV-11618-PBS	)	Magistrate Judge Marianne B. Bowler

LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS SUPPORTING ABBOTT LABORATORIES INC.'S MOTION FOR SUMMARY JUDGMENT

Dated: August 28, 2009

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Pursuant to the Federal Rule of Civil Procedure 56 and Local Rule 56.1, Defendant Abbott Laboratories Inc. ("Abbott") submits this statement of material facts of record as to which there is no genuine issue to be tried, in support of its Motion for Summary Judgment.

I. THE PARTIES

1. The parties to this litigation are Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") and Defendant Abbott Laboratories Inc. ("Abbott"). (Case No. 07-CV-11618, the Complaint "Complaint," ¶¶ 12, 16, Ex. 1.)

II. VEN-A-CARE'S UNDER SEAL-COMPLAINTS AND CURRENT COMPLAINT REGARDING ERY DRUGS

2. In 1995, Ven-A-Care filed a suit under seal against various pharmaceutical manufacturers, including Abbott, alleging that defendants' "price spreads" (differences between AWPs and actual sales prices) amounted to fraud against the Medicaid and Medicare programs (the "DOJ case"). (1995 Complaint, Case No. 95-CV-1354 (S.D. Fla.), Ex. 2.)

3. This under-seal complaint in the DOJ case alleged that Abbott's Hospital Products Division ("HPD") violated the False Claims Act ("FCA") by reporting inflated prices for nineteen NDCs of infusion and injectable pharmaceutical products. (*Id.* ¶ 50.)

4. In 1997, Ven-A-Care added an allegation that Abbott marketed the spread to increase its market share of the drugs at issue. (Second Amended Complaint filed August 13, 1997, ¶¶ 48-50, Ex. 3.)

5. In 2002, Ven-A-Care amended its under-seal complaint in the DOJ case to add several Abbott oral erythromycin ("Ery") drugs produced by Abbott's Pharmaceutical Products Division ("PPD"). (Ex. 6 to Fourth Amended Complaint, filed December 11, 2002, Ex. 4.)

6. The Department of Justice intervened in Ven-A-Care's complaint in March 2006 with respect to four Abbott products: Vancomycin, sodium choloride, sterile water and dextrose.

(2006 DOJ Complaint, Ex. 5.) Ven-A-Care amended its complaint to drop the Ery drugs and all but the four HPD products. (*U.S. ex rel. Ven-A-Care of the Florida Keys, Inc v. Abbott Laboratories Inc.*, Case No. 95-CV-1354, Plaintiff Ven-A-Care's Motion for Leave to Amend Complaint by Adopting United States' Complaint in Intervention (March 17, 2006), Ex. 6.)

7. On April 10, 2000, Ven-A-Care filed a complaint under-seal in the United States District Court for the District of Massachusetts against several drug manufacturers (Case No. 00-CV-10698, the "Massachusetts Case."). Abbott was not named in that complaint. (2000 Complaint, Ex. 7.)

8. On February 15, 2001, Ven-A-Care filed an amended complaint adding Abbott to the Massachusetts case. (First Amended Complaint, Ex. 8.)

9. The First Amended Complaint named six Ery drugs (thirteen National Drug Code ("NDCs")) and alleged that Abbott and the other drug manufacturers "falsely represented the prices that they charged wholesalers for certain of their generic prescription products." (*Id.* at ¶ 1.)

10. The First Amended Complaint alleged that this "wholesaler information" was "used to determine the Wholesaler Acquisition Cost (WAC) for the specified drugs to which a percentage was added to estimate the acquisition cost of a pharmacy purchasing from a wholesaler." (*Id.* at ¶ 3.) The First Amended Complaint identified eight states (Alabama, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas) as "WAC STATES" that utilized Abbott's allegedly false WAC information. (*Id.* at ¶ 2.)

11. The First Amended Complaint further alleged that the Defendants "knew that the WAC STATES' Medicaid Programs relied on the DEFENDANTS' representations of the prices

that the DEFENDANTS charged wholesalers in setting the amount to be reimbursed to a pharmacy. (*Id.* at ¶ 3.)

12. The First Amended Complaint made no allegations with respect to published Average Wholesale Prices ("AWPs") or the other forty-one State Medicaid Programs. (*Id.*)

13. On February 1, 2002, Ven-A-Care filed a Second Amended Complaint, adding an allegation that, "[t]hrough its direct prices," Abbott also knowingly defrauded California Medicaid. (Second Amended Complaint ¶ 141, Ex. 9.)

14. The Second Amended Complaint made no allegations directed to Abbott with respect to published AWPs or the remaining forty State Medicaid programs, although Ven-A-Care did add AWP-based allegations directed to the other defendants. (Second Amended Complaint ¶¶ 155, 178, Ex. 9.)

15. On February 15, 2005, Ven-A-Care filed its Third Amended Complaint under seal. In this amended complaint Ven-A-Care alleged for the first time that Abbott caused the publication of false AWPs for the Ery drugs in addition to false WACs and direct prices. (Third Amended Complaint ¶ 194, Ex. 10.)

16. The Third Amended Complaint expanded Ven-A-Care's claims from nine States to all state Medicaid programs nationwide. (*Id.* at ¶ 171, Ex. 10.)

17. The Third Amended Complaint also named five additional Ery formulations (13 NDCs). (Ex. 1 to Third Amended Complaint, Ex. 10.)

18. Because these complaints were filed under seal, Abbott had no knowledge of them. *See* 31 U.S.C § 3730(b)(2).

19. On August 30, 2007, Ven-A-Care severed its claims against Abbott and filed the current complaint (Case No. 07-CV-11618, the "Complaint," Ex. 1.) The United States declined intervention. (*Id*. at ¶ 15.)

20. The Complaint named six additional Ery formulations (17 NDCs), bringing the total to seventeen Ery formulations (43 NDCs). (Complaint ¶ 33, Ex. 1.)

21. The Complaint alleges that Abbott violated the FCA by "report[ing] inflated pharmaceutical prices that it knew Medicaid relied upon to set reimbursement rates for Abbott's pharmaceutical products" when its "actual sales prices . . . were far less than the prices reported." (Complaint at Intro, Ex.1.) The Complaint also alleges that Abbott "used the public fisc as a marketing tool, actively promoting government-funded 'spreads' between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. These efforts allowed Abbott to increase its profits by boosting sales for its drugs." (*Id*.)

22. The Complaint alleges two causes of action under the FCA. Count I alleges that "Abbott knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States" by "knowingly using the spread [between reported prices and providers' actual acquisition costs] as an unlawful inducement in violation of the federal anti-kickback statute" and that Abbott violated 31 U.S.C. § 3729(a)(1). (*Id.* at ¶ 72.) Count II alleges that "Abbott knowingly made, used, or caused to be made or used, false records or statements to cause false or fraudulent claims to be paid or approved by the United States" and that Abbott violated 31 U.S.C. § 3729(a)(2). (*Id.* at ¶ 75.)

23. Ven-A-Care seeks damages from January 1, 1994 through the present. (*Id.* at ¶ 49.)

24. Dr. John Lockwood, the designated corporate representative for the Rule 30(b)(6) deposition of Ven-A-Care in this case, provided the following testimony regarding Ven-A-Care's various amendments to the Complaints:

> Q. And the complaint that you filed in February '01 -- well, let me back up -- go forward, rather. In February 2005 you added additional Abbott Ery NDCs to complaint, right?
>
> A. Yes, sir.
>
> Q. Why were you adding additional NDCs four years later?
>
> A. I think our original thought process was to call the attention of the government to drugs where the FUL potentially was affected by I guess the WAC fraud that we saw and by -- of a later date we, I guess, felt that the WAC fraud would stand on its own, to the extent that we could show it and prove it. And I think we were trying to show the government the impact on the FUL in 2001 and that the impacts were far-ranging. I think that was our goal at that time.
>
> Q. And then you added additional Abbott Ery NDCs to the complaint in August of 2007, so over two years after the previous amendment and I guess six years after originally filing this complaint. Why was Ven-A-Care adding those NDCs at that time?
>
> A. I think my recollection is that we felt that those drugs would also be properly included in the allegations that we made in the complaint.
>
> Q. Well, when -- those NDCs -- and I won't list all of them, the ones added in 2007, but they are, for example, the EES 400 film tab; the Ery tab tablet, 250 milligrams; EES granules, 250 – 200 milligrams. I'm just giving some examples. When did you -- for the drugs that you added in August 2007, when did you discover the alleged fraud that you were stating in the complaint with respect to those NDCs?
>
> A. Well, I'd have to go back and look, but I believe all of those NDCs are actually included in the Econolink database and shows some pricing discrepancies. Along the way we were, I think, trying to point out what we thought were the bad actor drugs, the most -- the most -- the significant problem drugs, and along the way we included more drugs that may or may not have quite as big a spread or for one reason were ignored or not focused on.

> Q. Was this a situation where -- and I just want to understand the process for adding these along the way, where you discovered the price discrepancies back in 2000 for all of these NDCs and then added them for different reasons over time?
>
> A. That would be my general answer that, yes, it was -- we had pricing information over a period of time and I think our reasons for adding them changed over time in our discussions with the attorneys.
>
> Q. So you explained the reason for adding -- for the second addition where those weren't necessarily affecting the FUL and you were more focused on the FUL. Can you explain the addition of the third time?
>
> A. I probably went over the -- I know I went over the list again and made basically final decisions with the attorneys about which drug should be in and which drug should be out and discussed that and proceeded from there.

(04/24/09 30(b)(6) Lockwood Dep. ("30(b)(6) Ven-A-Care Dep.") at 434:18-437:18, Ex. 11.)

III. PUBLIC DISCLOSURE REGARDING ERY DRUGS

25. In September 1984, the HHS-OIG issued a report titled "Medicaid – Limitation on Payments for Drugs." (Ex 12.) According to the report: "Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price." (*Id*. at 10.193.) Included in this report was a comparison of the Bluebook AWP and the 70th Percentile Price based on data collected from an audit of pharmacy invoices for EES 400® tabs. According to the report, the AWP for EES 400® was $21.95 and the 70th Percentile Price per Audit was $16.49, resulting in a spread of 33%. (*Id*. at 10.203.) The report also listed prices generally paid by pharmacies in different states. (*Id*. at

Schedule V.) According to the report, the median price paid by pharmacies in Massachusetts for EES 400® tabs was $14.06, resulting in a spread of 56%.[1] (*Id.*)

26. On September 17, 1986, the State of Colorado Department of Social Services wrote to HCFA, the federal agency responsible for Medicaid regarding proposed regulatory changes concerning maximum limits for generic drugs, and warned that pharmaceutical manufacturers were using spreads on drug prices as a "marketing tool": "Published data in Red Book or Blue Book should be used with caution. Market surveys of various brands of generics should be used to verify accuracy of the data. . . . Submission of artificially high AWP prices has been used as a marketing tool by the generic companies to sell their products." (Ex. 13 at 4.)

27. On July 5, 1987, the *Lexington Herald-Leader* published an article titled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." (Ex. 14.) The article stated that "Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor." (*Id.* at 1.) The article stated that "[t]he system is distorted even further by drug companies that publish prices that are dramatically higher than the prices they actually charge pharmacies." (*Id.*) In one example, the article stated that, as a result of a 1985 survey, Texas Medicaid officials learned that "one brand of penicillin . . . had a Red Book price of $100 'but pharmacists were buying it all day long for $30.'" (*Id.* at 7.) In another example, the article stated that Kentucky Medicaid officials "discovered that [an arthritic medication] was being sold to pharmacies for only 8.88 cents a tablet—47% below the published Average Wholesale Price."

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[1] The spreads represented in Ven-A-Care's Complaint are in effect exaggerated by 100%. For example, based on Ven-A-Care's method of calculating spread in the Complaint's Exhibit A, even if a drug's AWP is only 5% more than the "relator's cost," Ven-A-Care would claim that drug has a 105% spread. For consistency and to enable valid comparisons, this brief will utilize a proper calculation of spread ((AWP-AAC)/AAC or (AWP/AAC)-1.0).

(*Id.* at 4.) The article also discussed a "sales technique called 'playing the spread,'" noting that a large "spread, or difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit." (*Id.* at 4-5.) The article stated that some "companies actually advertised that they had a better spread," and "many companies routinely list Average Wholesale Prices and 'your price' in their catalogs to show the spread." (*Id.* at 5.) The article indicated that previous attempts to change the system had "met bitter resistance from the National Association of Retail Druggists" and other groups, who "led the fight to force the federal Health Care Financing Administration . . . to retreat from proposed changes in 1985 that came up after the inspector general's audit discovered the overpayments." (*Id.* at 8-9.)

28. In March 1991, the HHS-OIG issued a report entitled "Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs In the United State and Canada." (Ex. 15) This report focused on the "most commonly used drugs" and found: "over half of the commonly used drugs had lower prices in Ontario." (*Id*. at ii.) According to the report, the Ontario price for Erythromycin Tab 250 mg was 55.3% lower than the HFCA FUL. (*Id.* at B-2.)

29. On July 31, 1992, the Energy Commerce Committee of the U.S. House of Representatives held a hearing to discuss "Bills to Amend the Public Health Service Act and the Social Security Act to Establish Limits on Certain Drug Prices." (Ex. 16.) John M. Rector, Vice President of Government Affairs and General Counsel for the National Association of Retail Druggists ("NARD"), submitted a statement at the hearing. (*Id.* at 280.) NARD also submitted a comparison of the contract prices (available to members of its organization) and published AWPs. (*Id*. at 302-310.)

30. Several versions of Abbott's Erys at issue in this case were on NARD's list presented to the U.S. Congress, including EES 400® TABs, EES® 200 liquid, EES 400® liquid,

Ery-TAB® 250 mg tabs, Ery-TAB® 333 mg, and Ery-TAB® 500 mg. (*Id.*) The price lists show discounts for these drugs ranging from AWP-56% to AWP-86% (spreads of 127% to 614%). (*Id.*) These spreads, publicly disclosed in 1992, equal or exceed the spreads alleged by Ven-A-Care on the same drugs a decade later. The following table compares the spreads shown in this 1992 Congressional Report and the spreads alleged in Ven-A-Care's Complaint.

Drug	1992 Congressional Report AWP	1992 Congressional Report Contract Cost	Spread Disclosed in 1992	Ven-A-Care Alleged Spread
E.E.S.® 400 tabs	$104.12	$46.25	125%	58%
E.E.S.® 200 liquid	$19.59	$8.00	145%	64%
E.E.S.® 400 liquid	$36.49	$15.45	136%	79%
Ery-Tab® 250 mg tabs (100)	$23.75	$3.51	577%	178%/249%
Ery-Tab® 250 mg tabs (500)	$112.81	$17.43	547%	242%
Ery-Tab® 333 mg tabs (100)	$34.97	$4.78	632%	147%/218%
Ery-Tab® 333 mg tabs (500)	$166.12	$23.78	599%	211%
Ery-Tab® 500 mg tabs (100)	$40.10	$12.78	214%	132%/154%
Erythrocin® 250 mg (500)	$65.31	$24.75	164%	109%
Erythrocin® 500 mg (100)	$24.86	$11.89	109%	98%
Pediazole® suspension (100 ml)	$13.99	$4.23	231%	69%
Pediazole® suspension (200 ml)	$27.29	$8.37	226%	69%
Pediazole® suspension (250 ml)	$33.61	$10.50	220%	70%

31. In August 1994, at HCFA's request, the Office of Inspector General (the "OIG") commenced an audit surveying drug prices. (6/24/08 Chesser Dep. at 66:1-9; 89:2-4, Ex. 17.) The results of this study were published in a 1997 OIG report titled Medicaid Pharmacy – Actual

Acquisition Cost of Generic Prescription Drug Products. (*Id.* at 87:19-88:11; Ex. 17.) The objective "was to develop a nationwide estimate of the discount below AWP at which pharmacies purchase generic drugs." (*Id.*) As part of its study, the OIG collected over 9000 invoice prices for generic drugs. (*Id.*) Based on the audit, the OIG "estimated that, on average, actual acquisition cost of generic drugs was 42.5 percent below AWP [a 74% spread]." (*Id.*) In its comments to the report, HCFA concurred with the OIG's findings and stated that "[t]he findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies." (*Id.* at App. 3, Pg. 2.) The OIG Working Files reflect audits of actual invoices containing Ery-Tab prices. (Working Files, Ex. 22.)

32. On June 10, 1996, *Barron's* published an article entitled "Hooked on Drugs," which detailed not only an alleged spread between Abbott's reported AWP and its prices for certain of its generic drugs, but also stated that drug manufacturers, including Abbott, employed "drug salespeople . . .[that] let[] the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm." (Ex. 18 at 3.)

33. In March 1997, various representatives of state Medicaid programs and an HHS-OIG investigator, Paul Chesser, attended a Medicaid Pharmacy Administrators Symposium in Asheville, North Carolina. (Ex. 19.) At least one meeting was held to obtain input from state Medicaid administrators about basing rebates on AWP rather than AMP. (*Id.* at 1.) The record of discussion notes that one reason offered in support of basing rebates on AWP was "that those drug manufacturers that play games with AWP (overstate AWP for marketing purposes) would immediately lower their AWPs to a more realistic level."

34. In May 1998, an OIG report titled "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" reiterated that "[b]ecause AWP is usually used as a basis for reimbursement at the pharmacy level, manufacturers can use it as a marketing tool to gain market share." (Ex. 20 at 5.) This report goes on to acknowledge that "[t]he drug industry currently treats AWP as a published list price rather than a true wholesale price." (*Id*.)

35. On November 29, 2001, the HHS-OIG published "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Texas Health and Human Services Commission." (Ex. 21.) This report stated that the average pharmacy acquisition cost for generic drugs was AWP-62.84% and WAC-26.13%. (*Id.*.)

36. On March 14, 2002, the HHS-OIG published "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products." (Ex. 23.) This report found that "there is a significant difference between pharmacy acquisition cost for generic drugs and AWP." The estimated actual acquisition cost was 65.93% below AWP.

37. In 1998, under contract from the State of Idaho, Myers and Stauffer prepared a report analyzing the acquisition cost of prescription drugs in the state of Idaho. (Ex 24 at 4.) Myers and Stauffer utilized invoices collected from studies of Arkansas and Kentucky and weighed the data to Idaho Medicaid utilization. (*Id.*) This report found that the "average discount from AWP for multi-source drugs was 65%. (*Id.* at 5.) The report also included a table of "Idaho Weighted EAC Discounts." This table included Ery-TAB (NDC 00074632013) and listed its AAC and the AWP. (*Id.* at 18.) According to this report, the invoices collected from pharmacies indicated that the average price paid for Ery-TAB was AWP-65.5%, or 33.50% of AWP. (*Id.*)

38. In 1998, under contract from the Kentucky Department for Medicaid Services, Myers and Stauffer prepared a report on the cost of dispensing prescription medications to Kentucky Medicaid recipients. ("A Survey of Dispensing Prescriptions and Estimated Acquisition Cost in the State of Kentucky" Ex 25 at 1.) This report found that pharmacies were able to obtain discounts from multi-source drugs that had a MAC price at a discount of AWP-72.6%. (*Id*. at 22.)

39. In March 1999, under contract from the Wyoming Division of Health Care Financing, Myers and Stauffer prepared a report titled "A Survey of Dispensing and Estimated Acquisition Costs of Pharmaceuticals in the State of Wyoming." (Ex. 26.) According to this report, the actual acquisition cost of multi-source drugs that had a MAC price, had an average discount of AWP- 73.7%. (*Id.* at 23.) Ery-Tab ® (NDC 00074632013) was included in this study. (*Id*. at 21.)

40. In 1999, under contract from the Louisiana Department of Health and Hospitals, Myers and Stauffer prepared a report, titled "A Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of Louisiana" analyzing the pharmacy dispensing costs and drug acquisition costs for providers serving Louisiana Medicaid beneficiaries. (Ex. 27) This report found that pharmacies were obtaining a discount of AWP-45.5% through AWP-62.8% for multi-source drugs. (*Id*. at 42.)

41. In 2002, under contract from the California Department of Health Services, Myers and Stauffer prepared a report titled "A Survey of Acquisition Costs of Pharmaceuticals in the State of California." (Ex. 28 at 3 .) This Report found:

> Findings from the study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In

> fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10. These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement.

(*Id*. at 4-5.)

IV. VEN-A-CARE'S "DISCOVERY" OF ITS ERY CLAIMS

42. Ven-A-Care has not seen a patient or submitted a claim for payment from any health care program since approximately 1998. (12/6/07 Lockwood Dep. at 198:16-22, Ex. 29.)

43. Ven-A-Care did not have a specific conversation with an Abbott employee who marketed the spread to them on Erythromycin oral drugs. (30(b)(6) Ven-A-Care Dep. at 106:4-7, Ex. 11.)

44. Ven-A-Care never witnessed an Abbott employee marketing the spread on any Ery drug. (*Id*. at 183:15-184:6, Ex. 11.)

45. Ven-A-Care does not have any evidence that Abbott knew that any wholesaler was marketing the spread on any Ery drug or that Abbott ever directed its customers to the spread information published by any wholesaler. (*Id*. at 177:22-178:11, 280:4-22, 287:11-14, Ex. 11.)

46. Ven-A-Care has no record that it ever purchased any of the Erythromycin products. (Ven-A-Care's Second Amended Answers to Interrogatories, Response No. 1, Ex. 30.)

47. Ven-A-Care began investigating the alleged spreads on Ery drugs in 2000:

> Q. What led you to look at the Abbott drugs at that point in 2000 as opposed to sometime in 1999 or 1998?
>
> A. Well, this isn't the only thing I was doing at Ven-A-Care. We had a wide variety of projects going on. I certainly had a wide variety of projects going on at any one time and it was just a matter of, I guess, what we had time to look at in terms of investigating and looking at these issues. And I looked at -- happen to look at

> Abbott in more detail in 2000, and in many ways, this complaint describes what I found.

(30(b)(6) Ven-A-Care Dep. at 21:4-15, Ex. 11; *see also id.* at 40:8-40:22, Ex. 11.)

48. Ven-A-Care claims that, although it might have been able to piece together information from documents earlier, it did not "discover" Abbott's alleged fraud with respect to the Erys until 2000. (*Id*. at 22:10-23:9, Ex. 11.)

49. Ven-A-Care primarily used a copy of McKesson's Econolink software program to "discover" the claims. (*Id.; see also id* at 48:15-49:4.)

50. Ven-A-Care acquired its copy of Econolink in March 2000. (*Id*. at 222:12-22:3-15, Ex. 11.)

51. Ven-A-Care shared a copy of Econolink with the DOJ in January 2001 (without McKesson's permission or knowledge). (30(b)(6) Ven-A-Care Dep. at 227:12-228:9, Ex. 11.)

V. THE ERY DRUGS

52. Abbott's different Ery formulations consist of different drugs that use the same antibiotic salt compounds. (Meditz Affidavit ¶ 5, Ex. 31.) Each formulation is prescribed for different purposes and to different types of patients. (*Id.* at ¶ 6.) Each formulation faces competition from different drugs. (*Id.*¶.) For example, Pediazole Suspension is prescribed for, and used by, only pediatric patients. (*Id.* at ¶ 7.) By contrast, Ery-TAB® is prescribed for and used by adult patients. (*Id.*.)

53. Abbott PPD reported the product's WAC and list price to the pricing compendia at the product's launch. (2/19/09 Parker Dep. at 55:20-56:7, Ex. 32.) Abbott also reported to the pricing compendia whenever Abbott took a price change to the WAC or list price of a product. (2/17/09 Fiske Dep. at 158:5-16, Ex. 33.)

54. During the fifteen-year time period relevant to Ven-A-Care's claims, Abbott changed and reported WACs and list prices for the Ery drugs to the compendia on only five occasions. (2/19/09 Parker Dep. at 105:3-11, Ex. 32.)

55. Abbott calculated and reported WAC as the price charged to wholesalers and other customers that purchased a case quantity or more of a product, prior to taking into account any possible chargebacks or discounts to which the wholesaler or customer would be entitled. (12/17/08 Senger Dep. at 34:17-35:3; 162:24-163:7, Ex. 34; 2/17/09 Fiske Dep. at 198:12-19, Ex. 33.)

56. Abbott's list price was the price charged to any non-contract customer that purchased less than a case quantity of product. (12/17/08 Senger Dep. at 145:24-146:5, Ex. 34.)

57. Mr. Fiske described the factors Abbott used in setting the prices for Erythromycin products: "We evaluated a number of things in terms of the pricing of the erythromycins, we evaluated the competitive circumstances in the marketplace, we evaluated our own market share for the products and determined if we felt we could take price actions. (2/17/09 Fiske Dep. at 41:8-12, Ex. 33.)

> Q. Prior to July of 2003 for the erythromycin products, how were the WAC prices that were published by Abbott to the compendia such as First DataBank and Red Book set?
>
> A. I -- I think I testified to this already today. I think that I explained that we evaluate competitive circumstances in the marketplace. It's no different for WAC pricing than it is for contract pricing, because, remember, we always have customers that are purchasing at WAC and list price and we want to maximize our margins. We evaluated the -- we evaluate the competitive situation, what kind of market share do we have for our products, what has inflation been over time. In -- in this case, we al- -- we also look at the WAC pricing for our competitors. It's hard to discern contract pricing for competitors. That information is not readily available. But after we have done that, we determine if there's an opportunity to take a price increase. I told you that we took a total of five price increases from 1994 to present.

(*Id*. at 80:2-24, Ex. 33.)

58. "List price" is defined by Merriam-Webster's Dictionary as "a basic price of an item as published in a catalog, price list, or advertisement before any discounts are taken." (Merriam-Webster's online dictionary at http://www.merriam-webster.com/dictionary/list%20price (last visited on July 25, 2009).)

59. A variety of sources defined WAC as an undiscounted list price:

(a) The September 2001 GAO Report "Medicare, Payments for Covered Outpatient Drugs Exceed Providers Cost" defined WAC as "the list price a wholesaler pays to a manufacturer, but it does not include discounts that may affect the net price." (Ex. 35.)

(b) Redbook defined WAC as the "manufacturer quoted list price to wholesale distributors, and does not with any deal terms or specialized contract pricing." (Minne Ex. 82, Ex. 36.) Kristin Minne, Rule 30(b)(6) representative for Redbook, defined WAC as a price that "does not reflect rebates and contract pricing and, you know, discounts for early payment, [etc.]" (11/19/08 Minne Dep. at 396:9-19, Ex. 37.)

(c) The U.S. Congress defined WAC in the Medicare Modernization Act of 2003:

> The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . ..

(42 U.S.C. § 1395w-3a(c)(6)(B), Ex. 38)

60. Abbott had sales of Ery drugs at both its published WACs and list prices. (12/17/08 Senger Dep. at 52:11-23; 171:5-172:2, Ex. 34; 1/15/09 Lehn Dep. at 214:23-215:10, Ex. 39; 2/17/09 Fiske Dep. at 48:4-25; 63:21: 64:1; 238:5-10, Ex. 33.)

61. Since 1991, Abbott has reported its average manufacturer price ("AMP") directly to CMS (f/k/a HCFA) for all of its products, including Ery products, on a quarterly basis as required by the Medicaid Rebate Act. 42 U.S.C. 1396r-8. (2/18/09 Fiske Dep. 351:14-15, Ex. 33.)

62. While Abbott PPD submitted WACs and list prices for the Ery drugs, the compendia actually calculated the AWPs for them. (2/17/09 Fiske Dep. at 143:23-144:1, 175:16-23, Ex. 33.)

63. Abbott informed Redbook on many occasions that it never intended to control the AWP published by the pricing compendia. (*See* Gerzel Ex. 10 ("Abbott does not control how Red Book does its business nor does Abbott provide AWP or a calculated markup to establish an AWP. Consequently, Abbott concluded that there was no need to respond to Ms. Voeck's April 2003 letter. Abbott trusts that Red Book will continue to conduct its business as it sees fit.") *See also*, 10/20/09 Gerzel Dep. at 127:5-129:14, Ex. 41 ; 02/17/09 Fiske Dep. at 142:18-144:12, Ex. 33.)

64. Abbott's PPD employees testified that they believed that they reported the prices that the pricing compendia wanted and in accordance with Abbott's use of the terms:

(a) Joseph Fiske, Director of Pricing and Planning, testified:

> A. The information that we reported to the data agencies was our WAC and our list price. Any changes to our WAC and list price, we did so in good faith with the expectation that that was the information we should be providing. Nobody told us to do anything differently than that, including Kay Morgan who certainly had the opportunity because she knew what our practices were.

(2/17/09 Fiske Dep. at 166:24-167:7, Ex. 33.)

* * * * *

> A. The pricing that we reported to the pricing compendia were the WAC and the list price -- the published WAC and list price, the -- the WAC price before any discounts to any of our customers, including the wholesalers. That was our practice. We always acted in good faith by doing that. Nobody ever told us that we should do anything differently than that.

(2/17/09 Fiske Dep. at 195:7-14, Ex. 33.)

> * * * * *
>
> The WAC price and the list price that we reported to the data agencies was a price that customers paid for our products. It was a price that was generally available in the marketplace. There was no intent to misrepresent anything.

(2/17/09 Fiske Dep. at 197:2-6, Ex. 33.)

> * * * * *
>
> (b) April Gerzel, a PPD Pricing Analyst testified:
>
> Q. Do you have any idea at all why Abbott was reporting prices to the compendia?
>
> A. I believe that's what our obligation was that they wanted us to report to them.
>
> Q. (BY MR. ANDERSON): How did you gain that understanding?
>
> A. Through my training, when I came to the position.
>
> Q. What was the obligation?
>
> A. To inform the pricing compendia of new product launches, price changes to list or WAC, or any discontinued products that we were no longer going to manufacture and sell.

(2/20/09 Gerzel Dep. at 44:24-45:13, Ex. 41.)

65. Kay Morgan worked at Abbott from 1975 to 1999. (8/27/07 Morgan Dep. at 27:17-20, Ex. 42.) She then went to First DataBank and served as Manager of Editorial Services. (*Id*. at 28:19-22, Ex. 42.) Ms. Morgan was responsible for the pricing information published by First DataBank until she left in 2005. (*Id*. at 28:23-29:11, Ex. 42.)

66. Abbott denies marketing any price spreads on the Ery drugs. For example Mr. Fiske, Russ Lehn and Ms. Parke testified as follows:

> Q. (BY MR. ANDERSON): Did Abbott provide spreads by reporting high inflated estimated AWPs or AWPs to the pricing compendia?
>
> MR. BERLIN: Objection, form.
>
> A. No.
>
> Q. (BY MR. ANDERSON): With respect to the erythromycins that were selling for much less than the AWPs, will you agree that Abbott was enabling chains to achieve more reimbursement spread on those drugs?
>
> MR. BERLIN: I'm sorry. Could I have the question back?
>
> (Requested testimony read back.)
>
> MR. BERLIN: Objection, form.
>
> A. No.
>
> Q. (BY MR. ANDERSON): Why not?
>
> MR. BERLIN: Objection, form.
>
> A. Numerous reasons. As I've indicated, we reported the WAC and the list price that we were actually selling product for in the marketplace. Some of those purchasers were, in fact, retailers. In addition, the actual reimbursement for the products in question were not a- -- not always even based on AWPs. There are, as we discussed previously, numerous formulas for determining what a maximum allowable cost will be for a product, and some of those have no relationship to AWP whatsoever. So the answer is "no".

(2/18/09 Fiske Dep. at 304:5-305:7, Ex. 33.)

> ***
>
> Q. Based on your experience, what factors did Abbott consider when setting prices for the erythromycin drugs?
>
> A. Competition, having a full line of product, quality of the product, dependable distribution, reliable distribution, distribution cost, cost of the product.

Q. Did you ever observe anyone at Abbott consider the reimbursement spread when setting prices for erythromycin?

A. No.

Q. Did you ever observe that Abbott increased the list price, or the WAC, for any of the erythromycin drugs in order to increase the reimbursement spread?

A. No.

Q. To your knowledge, was that ever a consideration in price setting at Abbott?

A. Not to my knowledge.

Q. And I asked you about factors considered for setting price. What factors about Ery did Abbott market to its customers in the 1993 through '96 period?

A. Those that I mentioned earlier, other than the cost of the product.

Q. To your knowledge, did any Abbott employee market the spread between erythromycin's cost to the provider and the reimbursement amount?

A. Not to my knowledge.

Q. And did you ever learn that wholesalers were marketing the spread on the erythromycins? Did you have any specific knowledge of that?

A. No.

(1/15/09 Lehn Dep. at 217:18-218:23, Ex. 39.)

***

Q. (BY MR. ANDERSON): Have you ever heard AWP spread referred to as a potential talking point with customers?

A. No.

Q. Would that type of activity be condoned by Abbott?

A. No, it would not.

Q. Why not?

> A. It's not our business how they profit. We have to sell our product based on the merits of our product, which have to do with its clinical effectiveness, its availability, its, you know, reliability, and that's the methods that we use to sell our products.

(2/19/09 Parker Dep. at 97:23-98:11, Ex. 32.)

VI. MEDICAID PAYMENTS FOR ERY DRUG CLAIMS

A. FULs

67. On January 15, 1969, new regulations were enacted providing for federal financial participation in state medical assistance programs. (31 Fed. Reg. 1243, Ex. 44.) According to these regulations, payments for prescription drugs could be made under this program at a rate "defined by the State agency." (*Id*. at 1244.)

68. The Federal Upper Limit ("FUL") program was established by the Secretary of Health and Human Services in 1987. (*See* 52 Fed. Reg. 28648, 28653 (July 31, 1987), Ex. 43.) The Secretary established the FUL program to allow "the Federal and State governments to take advantage of savings that are currently available in the marketplace for multiple source drugs . . . [while] maintain[ing] State flexibility in the administration of the Medicaid program." (Ex. 43.)

69. According to federal regulation, A FUL is established for a drug if:

> (1) All of the formulations of the drug approved by the [FDA] have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*;
>
> (2) At least three suppliers list the drug [in the FDA publication] based on all listings contained in current editions [or updates] of published compendia of cost information for drugs available for sale nationally.

(52 Fed. Reg. at 28658, Ex. 43.)

70. The FUL represents an amount set by CMS that is pertinent to what an agency may reimburse pharmacies, not including the dispensing fee, for a drug on the FUL. (52 Fed.

Reg. at 28653, Ex. 43.) FULs are set by CMS. Regulation instructed CMS to set FULs by computing a price "equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or in the case of liquids, the commonly listed size." (*Id.*)

71. FULs were in place for Medicaid payments to pharmacies for dispensing multisource, oral erythromycins. (Reisetter Report ¶ 48 Ex. 45; Redbook listing 1998, 2000 and 2001 (noting the FUL price (as "HCFA") for Erys, Ex. 46; Ven-A-Care 30(b)(6) Dep. at 221:3-19, Ex. 11.)

72. A FUL for an erythromycin drug prevented a pharmacy from increasing its Medicaid payment by submitting a claim for an erythromycin with a higher AWP than another generically equivalent erythromycin had. (5/1/09 Perri Dep. at 109:3-20, Ex. 47; *see also* 2/17/09 Fiske Dep. at 164:1-6 ("You have to keep in mind that the erythromycin products were multisource pharmaceuticals and often third-party payors, whether it be government agencies or others, don't reimburse based off of an AWP. They actually reimburse based on some MAC formula.") Ex. 33.)

B. CMS Exercised Discretion and Disregarded Published Prices in Setting FULs

73. Sue Gaston was the CMS employee responsible for setting FULs from April 1991 through February of 2003. (1/24/08 Gaston Dep. at 40:7-40:10, Ex. 48.) Gail Sexton was the CMS employee responsible for setting FULs beginning in 2004. (05/20/08 Sexton Dep. at 49:13-50:21, Ex. 49.)

74. According to Ms. Gaston, CMS utilized a computer program and then a manual review to establish the FULs. (1/24/08 Gaston Dep. at 232:22-234:6, Ex. 48.)

75. Ms. Gaston further testified that the manual review process was used to determine whether the price was "truly available or not" and whether or not "you should follow up and see if it's available." (*Id*. at 229:8-230:14, Ex. 48.)

76. According to Ms. Gaston, CMS did not always set the FUL based on the lowest reported price of the drug for which the FUL capped payment. For example, CMS would exercise discretion to set a higher FUL to ensure Medicaid patients access to pharmaceuticals. (3/19/08 Gaston Dep. at 451:12-451:19, 498:16-499:9, Ex. 48.)

77. CMS officials received feedback from members of the pharmacy community and from State Medicaid agencies about: "whether they felt that the FUL prices or the drugs were correctly on the FUL list or needed [to be] adjust[ed]"; whether the product was "available"; and whether "the pricing appears to be either too low or too high." (*Id*. at 433:14-434:8, 435:8-435:11, Ex. 48; 5/20/08 Sexton Dep. at 110:14-110:21, Ex. 49.)

78. The process CMS utilized in establishing FUL prices was recently the subject of a tutorial hearing before Judge Saris in the New York Counties Consolidated Cases. During that hearing, the Court acknowledged that CMS violated the regulation establishing the process for CMS to set FULs. (July 28, 2009 Tutorial and Motion Hearing at 32:24-33:5, Ex. 50.)

79. CMS had access to AMP information that manufacturers, including Abbott reported to CMS. (3/19/08 Gaston Dep. at 528:1-528:3, Ex. 48.)

C. DRA 2006 Litigation

80. In 2006, Congress passed the Deficit Reduction Act ("DRA"), which amended the FUL statute, 42 U.S.C. § 1396r-8. This amendment required CMS to "substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price." Pub. L. No. 109-171 § 6001, 120 Stat. 4, 54-55 (2006).

81. As part of the implementation of the new FULs, states were directed to assure that dispensing fees paid by Medicaid programs to pharmacies were reasonable. (72 Fed. Reg. 39,142 (July 17, 2007), Ex. 51.)

82. The Congressional Budget Office estimated that calculating FULs at 250% of AMP would "reduce Medicaid spending by $3.6 billion over the 2006-2010 period and $11.18 billion over the 2006-2015 period. (Congressional Budget Office, *Cost Estimate: S. 1932: Deficit Reduction Act of 2005*, Ex. 52.)

83. On July 17, 2007, CMS published a final rule implementing the FUL formula established by the DRA. (72 Fed. Reg. 39,142 (July 17, 2007), Ex. 51.)

84. On November 7, 2007, the National Association of Chain Drug Stores ("NACDS") and the National Community Pharmacists Association ("NCPA") filed a complaint against the Department of Heath and Human Services, the Secretary of the Department of Health and Human Services, CMS, and the Acting Administrator of CMS asking for (among other things) an injunction to stop CMS from implementing the new FUL rule. (Complaint, *Nat'l Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Human Servs.*, No. 07-cv-02017-RCL (D.D.C. Nov. 7, 2007, Ex. 53.)

85. Dr. Stephen Schondelmeyer, one of Ven-A-Care's experts in this case, issued a statement in support of NCPA's request for an injunction. Dr. Schondelmeyer opined that the "AMP-based FULs, as described in the final rule, will result in payments to pharmacies that are below the pharmacy's actual costs for many generic prescriptions." Dr. Schondelmeyer stated the AMP-based FUL regulations would lower payments to pharmacies, result in "substantial losses" and endanger access to care. (Schondelmeyer Report ¶ 226, Ex. 54.)

86. On December 19, 2007, the court granted NACDS and NCPA's motion for a preliminary injunction and enjoined CMS from implementing the regulation effectuating the FUL formula established by the DRA. (Order of December 19, 2007, *Nat'l Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Human Servs.*, No. 07-cv-02017-RCL, Ex. 55.)

D. MAC

87. State Maximum Allowable Costs ("MACs") similarly capped Medicaid payments to pharmacies. (Steven Young, Ph.D. Report at 26 ("[A]t least twenty states performed their own determination of a MAC price to be paid for pharmacies for erythromycin."), Ex. 56.)

88. In this case and the DOJ case, discovery was conducted with respect to approximately half the State Medicaid agencies. Erythromycin products were found on the following 22 state MAC lists: Alabama, Arkansas, California, Delaware, Florida, Georgia, Idaho, Illinois, Kentucky, Maryland, Michigan, Missouri, Nebraska , North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Vermont, Virginia, Washington, Wyoming. (*See* Collection of MAC lists, Ex. 57; *see also* testimony from State Representatives: 12/2/08 Roxane Homar Dep. at 340:15-342:20 (Wyoming), Ex. 58; 12/11/08 Frank Tetkoski Dep. at 126:2-6 (Maryland), Ex. 59; Ex. 60 (Maryland 14); 12/2/08 Gary Cheloha Dep. at 308:3-8 (Nebraska), Ex. 61.)

89. State Medicaid programs used pricing information beyond manufacturers' prices reported in the pricing compendia to establish the MACs, such as:

(a) Invoice prices provided by pharmacies. (*See* Ohio: 12/15/08 Reid Dep. at 160:19-161:20, Ex. 62; Arkansas: 12/10/08 Bridges Dep. at 65:3-11, 244:14-245:9, Ex. 63; Maine: 3/26/2008 Walsh Dep. 97:20-98:14, Ex. 64.)

(b) Direct surveys of pharmacies and wholesalers. (*See* Nebraska: 12/02/08 G. Cheloha Dep. at 130:10-132:17, Ex. 59; Washington: 11/24/08 Hautea-Wimpee Dep. at

212:7-213:1 230:20-21, Ex. 65; North Dakota: 12/12/08 Joyce Dep. at 128:21-129:20, Ex. 66; Wyoming: 12/2/08 Homar Dep. at 214:6-12, Ex. 58.)

(c) Review of wholesaler catalogs and price lists: (*See* Tennessee: 3/12/08 Sullivan Dep. at 106:18-107:22, Ex. 67; Maryland: 12/09/08 J. Fine Dep. at 203:8-204:19, Ex. 68.)

90. Many State Medicaid officials confirmed that AWPs were not used to set MAC prices. (*See* Arkansas: 12/10/08 Bridges Dep. at 248:5-15, Ex. 63; Tennessee: 3/12/08 Sullivan Dep. at 115:20-116:10, Ex. 67; Maryland: 12/9/08 Fine Dep. at 320:2-10, 321:10-14, Ex. 68; 12/11/08 Tetkoski Dep. at 129:17-21, Ex. 59; Washington: 11/24/08 Wimpee Dep. at 226:16-227:9, Ex. 65; North Dakota: 12/12/08 Joyce Dep. at 109:20-110:10, 128-21-129:20, Ex. 66.)

91. For many states, MAC pricing (and pricing in general) was influenced by policy determinations and a give-and-take with providers to come up with levels that were fair under the circumstances. (*See, e.g.* Colorado: 12-15-08 Chapman Dep. at 46:1-17, 334-35, Ex. 59; Georgia: 12/15/08 Dubberly Dep. at 75:7-75:19, Ex. 70; Hawaii: 4/29/08 Donovan Dep. at 188:2-21, Ex. 69; Nebraska: 12/2/08 Cheloha Dep. at 125:20-126:12, Ex. 61; Wisconsin: 10/30/07 Collins Dep. at 82:8-83:7, 85:22-86:4, Ex. 71; *see also* Hughes Report ¶ 75, Ex. 72.)

92. Many State Medicaid agencies allowed for a profit margin in their MAC prices. (*See* Indiana: 12/3/08 Shirley Dep. at 410:10-18 (Indiana Medicaid established its MAC prices at 20% above the actual acquisition cost), Ex. 73; Massachusetts: 6/14/07 Jeffrey Dep. at 96:5-13 (Massachusetts Medicaid included profit margin in its MAC prices "in order to induce" pharmacy participation), Ex. 74 ; Wyoming: 12/2/08 Homar Dep. at 231:17-232:10 (Wyoming Medicaid set MAC prices 40% above the average actual acquisition cost in order to include a "profit" and to cover the "cost of running business"), Ex. 58; North Carolina: 10/21/08 Weeks

Dep. at 263:15-264:6 (North Carolina set MAC prices at 20% above actual acquisition cost.), Ex. 75; Minnesota: Myers & Stauffer Analysis ("SMACs are based on an informal survey of a few retail pharmacies that have agreed to share their costs. *The State tries to include an average profit of about $7.00 for each prescription using SMAC*. This $7 includes the $3.65 dispensing fee. . . ."), Ex. 76.; South Dakota: Dey Ex. 911 (South Dakota structured its MAC program "to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product."), Ex. 77.

VII. FEDERAL AND STATE TESTIMONY CONCERNING COMPENDIA PRICES

93. HCFA administrators from the relevant time period understood that AWP as reported in the compendia did not constitute an average of transaction prices. (*See* 7/13/07 Thomas Scully Dep. at 900:16-901:06, Ex. 78; 12/07/07 Elizabeth Richter Dep. at 152:9-13 (former Acting Director of the Center for Medicare), Ex. 79; 12/18/07 Robert Berenson Dep. at 72:19-73:03 (Former HCFA Deputy Administrator: "there was a common understanding within the agency that AWP referred to the prices in these compendia and that they deviated from actual acquisition prices and that's how we sort of viewed AWP."), Ex. 80; 10/29/07 Charles Booth Dep. at 310:9-15, 518:10-519:8 (Former Director of Office of Payment Policy: "I did not believe that there was a relationship to any great extent between acquisition costs and AWP."), Ex. 81.)

94. Federal officials involved in Medicare Part B and Medicaid drug payment policy, as well as OIG officials, knew well before 1994 that there were spreads between providers' acquisition costs and published AWPs. (*See e.g.*, 9/27/07 Larry Reed Dep. at 258:20-261:5 (Technical Director, CMS Medicaid Division of Pharmacy: "The saying that average wholesale price means 'ain't what's paid' has been around for a long long time."), Ex. 82; 4/23/07 Booth Dep. at 236:17-237:1 (CMS position was that AWP was inflated and overstated the price that

providers actually paid for the drug.), Ex. 80 9/13/07 Kathleen Buto Dep. at 433:4-18 (Former Director of CMS's Bureau of Policy Development: HCFA knew in 1991 that there was no predictable relationship between AWP and acquisition cost.), Ex. 83; 6/20/07 Robert Vito Dep. at 490:9-491:18 (Regional Inspector General: OIG reported to CMS that generic drugs sold at prices 60 to 90 percent below AWPs.), Ex. 84 ; 12/12/08 Ben Jackson Dep. at 394:6-395:10 (Acting Director, Operational and Program Reviews, Health Care Financing Audit Division, Office of Inspector General), Ex. 85.)

95. State officials understood that AWP was significantly higher than average transaction prices. *See* Tennessee: 3/12/08 Sullivan Dep. at 100:13-101:18 ("you could pay AWP minus 80 percent and still the pharmacist [would] make money for some"), Ex. 86; Alaska: 8/19/08 Campana Dep. at 93:15-95:16, 98:8-99:7 (Prior to 1990, Mr. Campana was aware "[t]hat the net cost to the pharmacy for generics that have been out for a long time was very low compared to the benchmark."), Ex. 86; California: 3/19/08 Gorospe Dep. at 212:16 – 213:17 (By August 1991, California knew that certain providers received discounts anywhere from 41 to 99 percent off of the published AWP.), Ex. 86 ; 9/22/08 Gorospe Dep. at 594:7-595:5 (By the late nineties California was aware that AWP minus 20 percent is significantly higher than the pharmacy acquisition costs for generic drugs.), Ex. 87; Florida: 12/15/09 Wells Dep. at 122:6-123:6, 206:2-206:15, 223:17-225:09, 339:20-341:02 (Providers able to receive discounts for innovator multisource drugs of 41.42 percent off of AWP; by 1990 AWP was no longer a reasonable predictor of the price for generic drugs.), Ex. 88; Illinois: 11/18/08 Parker Dep. at 182:1-5 (Change in reimbursement methodology prompted "due to Illinois Medicaid's realization that AWP had become virtually meaningless."), Ex. 108 ; Louisiana: 11/7/08 Terrebonne Dep. at 48:02-49:09 (It was a common statement within Louisiana Medicaid, and

other State Medicaid programs that "AWP equals ain't what's paid"), Ex. 89; Michigan: 3/25/08 Kramer Dep. at 93:5-94:2 (By 1992 Michigan Medicaid realized that some AWPs were upwards of 500 percent above acquisition costs.), Ex. 90.)

96. Some state Medicaid programs also designed their pharmacy payment methodologies to allow margin on ingredient costs in order to compensate for low dispensing fees. (*See e.g.* Delaware: 12/09/08 Denemark Dep. at 180:11-181:22 (Dispensing fees that were too low to cover the providers costs were not a problem due to a margin allowed on the ingredient cost), Ex. 91; Missouri: 11/07/07 McCann Dep. at 479:6-16 (same), Ex. 92.; New Jersey: DHS Inter-office Communication, Analysis and Evolution of New Jersey's Drug Reimbursement Program, 1/23/86, at 4, ("[Our program] compensated pharmacies for inadequate dispensing fees by allowing some 'fat' to exist in the pricing structure."), Ex. 93; Illinois: Illinois Dept. of Public Aid Memo, Briefing--Average Wholesale Prices (AWP) Pricing Changes, 5/30/00, at 2 ("We also expect arguments that dispensing fees should be increased to compensate for some of the revenue lost because of reductions in AWP."), Ex. 94.)

VIII. PROFFERED TESTIMONY OF MARK G. DUGGAN, PH.D.

A. Duggan's Opinions

97. On March 27, 2009, Ven-A-Care served the expert report of Mark G. Duggan, Ph.D. (Report of Mark G. Duggan, Ph.D, March 27, 2009 ("Duggan Rpt."), Ex. 95.) Duggan is a Professor of Economics at the University of Maryland. (*Id.* at 3.)

98. Prior to proffering expert opinion in the AWP litigation brought by the state of Texas, Duggan had never been retained to provide expert testimony in a court of law. (7/14/08 M. Duggan Dep. at 37:5-39:18, Ex. 96.) Apart from AWP litigation, Duggan has never been engaged to assess damages in civil litigation. (*Id.* at 41:6-13.) Duggan has never had a damage calculation accepted by a court of law or jury. (*Id.* at 376:3-7.)

99. In his March 27, 2009 report, Duggan summarized his expert opinion as follows:

> This Report calculates a **$15.559 million difference** between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicaid recipients during 1994Q1 to 2008Q1 period and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products.

(*Id.* at 2.)

100. Table 1 of Duggan's report listed his computation, using Abbott's direct transaction data, of the average price paid for each of the 43 Complaint NDCs. (Duggan Rpt. at Table 1, Ex. 95.) On average, the dollar difference between the AWP and the average price calculated by Duggan per prescription is about $3. (4/17/09 Duggan Ery Dep. 155:6-9, Ex. 97.)

101. Duggan has not proffered an opinion on what prices Abbott should have reported. (Duggan Rpt., Ex. 95.) Duggan merely reported a "difference." (7/14/08 M. Duggan Dep. at 44:8-45:6, Ex. 96)

B. Duggan's Calculations

102. For each quarter during the Q1-1994 to Q1-2008 time period, and for each of the 43 National Drug Codes at issue ("Complaint NDCs"), Duggan calculated the revised AWPs, WACs, and Direct Prices ("Direct Prices") that are used in his "difference" calculations. (Duggan Rpt. at 8, Ex. 95.) Duggan calculated the revised AWPs, WACs, and DPs by considering certain Direct and Indirect transaction data produced by Abbott. (*Id.*)

103. Duggan's report stated that he calculated the revised AWPs used in his "difference" calculation by "replacing AWP with 125 percent of the average pharmacy indirect price for each NDC in each quarter." (Duggan Rpt. at 9, Ex. 95.) For WAC, Duggan calculated the average price paid by customers who purchased through a wholesaler. (Duggan Rpt. at 8,

Ex. 95.) For Direct Price, Duggan calculated the average price paid by pharmacies who purchased directly from Abbott. (Duggan Rpt. at 9, Ex. 95.)

C. States and Periods With Some Data

104. In his report, Duggan performed separate Medicaid "difference" calculations for fifteen states: California, Texas, New York, Illinois, Florida, Kentucky, Georgia, Pennsylvania, North Carolina, Massachusetts, Louisiana, Michigan, Virginia, Wisconsin, and New Jersey. Duggan chose these states for which he performed separate "difference" calculations because they had high amount of expenditures of the 43 Complaint NDCs. (4/17/09 Duggan Ery Dep. at 101:21-102:2, Ex. 97.)

105. Table 28 of Duggan's report illustrates for which states and for which time periods Duggan used claims data. (Duggan Rpt. at Table 28, Ex. 95.) Duggan used claims data for only fifteen states: California, Texas, New York, Illinois, Florida, Kentucky, Georgia, Pennsylvania, North Carolina, Massachusetts, Louisiana, Michigan, Virginia, Wisconsin and New Jersey. (*Id.*) For none of the fifteen states did he have claims data for the entire period for which he calculated his "differences." (*Id.*) Instead of using claims data for the other thirty-four states and periods, Duggan calculated extrapolations. (4/17/09 Duggan Ery Dep. at 100:13-20, Ex. 97.)

106. Duggan's report separately explained the methodology that he used to calculate "differences" for the states of California, Texas, New York, Illinois, Florida, Kentucky, Georgia, Pennsylvania, North Carolina, Massachusetts, Louisiana, Michigan, Virginia, Wisconsin and New Jersey, for those time periods for which he had claims data. First, using the claims data, he identified the total number of claims for one of the 43 Complaint NDCs and then removed those claims with apparent data errors. (*E.g.*, Duggan Rpt. at 36, Ex. 95.) Second, Duggan developed a computer algorithm that purports to reflect the states' adjudication methodologies, using the

information contained in the Myers and Stauffer reimbursement schedules. (*Id.* at 36-37.) Third, he linked each of the states' claims for one of the 43 Complaint NDCs with a NDC-quarter-specific prices that he calculated. He utilized the prices he calculated from the three pharmacy classes of trade in Abbott's transaction data. (*Id.* at 39.) Fourth, Duggan then used his computer algorithm re-adjudicate those claims using his revised prices. (*Id.* at 39-40.) Anytime there was a difference between what the state paid on a claim and what it allegedly would have paid had Duggan's revised prices been used, Duggan computed a "difference" on that claim. (*Id.*) For example, Duggan even calculated a "difference" for claims reimbursed on the basis of a provider usual and customary charge ("U&C") or state MAC if his revised estimated acquisition cost price results in a price lower than the U&C or MAC. (Ex. 95.)

107. Duggan's report described the methodology that he employed to calculate "differences" for the quarters for which he did not have claims data for the fifteen states. (Duggan Rpt. at 31-35, Ex. 95.) Duggan computed a "ratio of DIFFERENCE" for the earliest quarter where he has claims data produced by the state. (*Id*. at 32) The "ratio of DIFFERENCE" or "difference ratio" purportedly reflects the percentage by which a states' spending for a specific NDC-quarter allegedly would have changed had Duggan's revised prices been used in a states' adjudication methodology. (*Id*.) Duggan then scaled down this ratio of DIFFERENCE to account for the possibility that the spread between reported prices and marketplace prices would have been less in earlier periods. (*Id*.) On an NDC-quarter basis, he applies this scaled ratio of DIFFERENCE to a state's putative spending for the 43 Complaint NDCs. (*Id.*) He utilizes aggregate data maintained by CMS, State Drug Utilization Data ("SDUD") and SMRF/MAX, to determine a state's putative spending for the 43 Complaint NDCs. (*Id.*)

D. States and Periods With No Data

108. Pages 89 through 92 of Duggan's report explain Duggan's methodology for extrapolating "differences" for the states for which Duggan had no claims data. (Duggan Rpt. at 89-92.) On an NDC-quarter basis, Duggan computed an average ratio of DIFFERENCE from his fifteen-state analysis. (Duggan Rpt. at 90, Ex. 95.) Duggan also referred to this value as a "DIFF-FRAC." (*Id.*) The "DIFF-FRAC" is a composite ratio of DIFFERENCE which represents the average ratio of the change in Medicaid spending that allegedly would have occurred if his revised prices had been used in the fifteen states' reimbursement calculations. (*Id.*) Each of the fifteen states which produced detailed claims data for an NDC-quarter was given equal weight in calculating the "DIFF-FRAC." States which did not produce any claims data for an NDC-quarter were given a weight of zero for that NDC-quarter. (*Id.*) Duggan then multiplied the composite "DIF-FRAC" by the total dollar expenditures for the Subject NDCs in each of the 34 no-data states to arrive at a dollar value "difference" totaling more than $5.2 million. (*Id*. at 89-92.)

E. Duggan's Medicaid "Difference"

109. Duggan did not analyze what impact, if any, the AWPs, WAC, or List prices for the Abbott Ery drugs reported in the compendia had on any FUL or state MAC. (Duggan Rpt. at 27 n.19 ("It is worth noting that I have not evaluated the effect of Abbott's published prices on the calculation of FUL or MAC prices."), Ex. 95.)

110. Duggan's "difference" calculations for Medicaid claims include a "differences" for claims that were, in fact, based on MACs. (4/17/09 Duggan Ery Dep. at 119:5-120:2, 120:22-121:10, 123:6-124:8 ("as I outline in my report, I do not account for the effect of a transaction-based AWP on the MACs or FUL prices. And [] it was not the focus of my analysis to determine the method that each state used in determining MAC prices."), Ex. 97.)

111. For those time periods for which Dr. Duggan had claims data for the 15 states for which he separately calculates a "difference," Dr. Duggan determined the percentage of claims that were reimbursed on the basis of provider charges. Duggan's analysis shows considerable variability within a given state over time in the percentage of claims reimbursed at U&C, and a general decline across the states in the percentage of claims reimbursed on that basis. For example, in Illinois, which produced a relatively full set of data, Duggan found that the percentage of U&C-based payments declined from 30% in 1994 to 2.06% in Q1 2006. (3/27/09 Duggan Electronic Production, pricesandunits.dta.)

112. Similarly, Duggan found that U&C-based payments in New York decreased from 44% in 1995 to 1.4% in Q1 2006. (3/27/09 Duggan Electronic Production, pricesandunits.dta.)

113. Although Ven-A-Care claims that Abbott's reported prices were "two or three times the cost of the drugs" and alleges "spreads" exceeding 100% (*see* Compl. ¶ 14, Ex. A, Ex. 1.), Duggan's aggregate "difference ratio" – the percentage Medicaid spending allegedly would have declined with Duggan's "corrected" compendia prices – is only approximately 25%. (Duggan Rpt. at 92, Ex. 95.)

F. Examples of Evidence Duggan Did Not Consider

114. Duggan relied upon the accounting firm of Myers and Stauffer to acquire information about the adjudication formulas used by state Medicaid programs to provide payments to providers for dispensing pharmaceuticals to Medicaid patients. (4/17/09 Duggan Ery Dep. at 121:16-122:10, Ex. 97.) To assist Duggan, Myers and Stauffer prepared schedules for each state Medicaid program titled "Medicaid Pharmacy Reimbursement Methodology" (*E.g.* California Medicaid Pharmacy Reimbursement Methodology, Ex. 98.)

115. Duggan did not consider evidence that some states, like Minnesota, intended to provide a profit for drugs on their MAC list or a profit to providers generally. (4/17/09 Duggan

Ery Dep. at 179:9-180:7 at 173:17-174:13, 182:13-184:2 ("Medicaid agencies are complicated things. There are many people and they're governed by their state legislatures and so forth. It's a complicated thing."), Ex. 97.)

116. Duggan did not evaluate whether state Medicaid programs intended to set MACs above the average transaction prices. (4/17/09 Duggan Ery Dep. at 174:4-13, Ex. 97.)

117. Duggan did not evaluate states' individual definitions of "usual and customary charge." (4/17/09 Duggan Ery Dep. at 124:9-125:1, Ex. 97.) The Myers and Stauffer reimbursement summary for the state of Massachusetts prepared for Duggan for this litigation states the following regarding the definition Massachusetts utilized for "usual and customary":

> Effective February 1st 1995 the definition of usual and customary was changed to be defined as the lowest price charged or accepted as payment for any given volume of drug (legend or non-legend) by an eligible pharmacy provider to any purchaser or reimburser.

(Myers and Stauffer Medicaid Pharmacy Reimbursement Methodology for Massachusetts, Ex. 99.) When asked if he was aware of this definition, Duggan testified that he did not "drill down" to determine whether the reporting of usual and customary by the pharmacies was "complete" and if that would have effected his "DIFFERENCE" calculation. (4/17/09 Duggan Ery Dep. at 132:3-21, 134:9-135:15, Ex. 97.)

118. Duggan did not analyze whether or not the dispensing fee that was paid by the Medicaid agency covered the cost of dispensing the 43 Complaint NDCs. (4/17/09 Duggan Ery Dep. at 165:19-166:10, Ex. 97.)

119. Duggan did not make any comparisons between the spreads for the 43 Complaint products and the spreads for similar drugs in the marketplace at similar time periods. (4/17/09 Duggan Ery Dep. at 184:3-11, Ex. 97.)

G. Improper Extrapolation

120. In its detailed protocols for Medicare Carriers, CMS instructs the Carriers to use "statistical sampling in their reviews to calculate and project [i.e., extrapolate] overpayment amounts to be recovered by recoupment, offset or otherwise." (CMS Manual System, Pub. 100-08, Medicare Program Integrity, Transmittal 114, *Change in Statistical Sampling Instructions* at 3.10.1.1, Ex. 100; *see also* Program Memorandum (Carriers), Transmittal B-03-022, *Use of Statistical Sampling for Overpayment Estimation When Performing Administrative Reviews of Part B Claims*, Ex. 101.)

121. Duggan did not use any of the sampling techniques – simple random sampling, systematic sampling, stratified sampling, or cluster sampling – recognized by CMS. (*Id* at 4.)

122. Two experts retained by Abbott, Dr. James W. Hughes (a Professor of Economics at Bates College) and Mr. Steven J. Young (an accountant with considerable healthcare consulting experience), have provided reports and deposition testimony detailing criticism of Duggan's extrapolated "differences." Those criticisms are summarized on pages 30-33 of Dr. Hughes's report and pages 24-27 of Mr. Young's report. (*See* Ex. 72, Expert Report of Dr. James Hughes); Ex. 56, Expert Report of Steven J. Young.)

123. Duggan's extrapolation assumes that the impact of his revised "but for" prices on Medicaid spending would be the same for claims paid by the 34 no-data states they were for the 15 states in his non-random sample. Yet Duggan did not determine which states established MACs for the Subject NDCs or compare the relative prevalence (or numerical values) of state MACs among the 15 and 34 state groups, respectively. (*Id.* at 27, n.1.) Duggan ignored these details and instead simply reviewed the basic adjudication formulas (*e.g.*, whether states used AWP, WAC, or DP) to establish comparability among the states. (Duggan Ery Dep. at 79:5-80:9, Ex. 97.)

124. In 2004, the OIG issued its report titled "Wide Variation in Medicaid Drug Prices." (Ex. 102.) Using 2001 data, OIG found that states' payment per unit for the same drugs varied widely: "On average the highest paying State paid 477 percent more per drug than the lowest paying State for each of the 28 drugs in our sample." (*Id.*) The OIG found much greater variation in reimbursements for generic drugs, with the median and average variations of 374% and 1230%, respectively, between the highest and lowest paying states. (*Id.*) Even the "average difference between the State at the 25th percentile and the State the 75th percentile (*i.e.*, the interquartile range) was 63 percent for the 10 non-innovator multisource drugs." (*Id.*)

125. The OIG reported that this variability was due to differences in state MAC pricing, as well as differences in states' definitions of "usual and customary charge" and the frequency with which drugs were reimbursed at U&C. (*Id.*) Specifically, the OIG stated: "*Even States with the same formula* for estimating pharmacy acquisition demonstrated variation in their average annual reimbursement prices," thus undercutting the "widespread assumption . . . that states with the same estimated acquisition cost formula pay similar prices." (*Id.* emphasis added).)

126. The suggested payments from Duggan's extrapolated difference calculation for the 34 no-data states often fall below actual acquisition costs:

(a) Maryland: for the second quarter of 2004, Maryland imposed a MAC of $9.57 for NDC 00074632613 (250 MG Erythromycin tablets). (Ex. 103 Maryland MAC List, DE_00019044-45.) Duggan ignored this MAC, as he does all MACs, and simply applied a composite "difference ratio" derived from his 15-state sample to the total expenditures made by Maryland to arrive at a dollar value "difference." (Duggan Rpt. at 90.) For the NDC-quarter (00074632613, Q2, 2004), Duggan applies a difference ratio of 19.918%. (3/27/09 Duggan

Electronic Production, scbc.dta.) In other words, Duggan reduces the payment on claims for this NDC- quarter by nearly 20%. Applying this difference ratio to Maryland's MAC-based payment for this product ($9.57) would lead to a per-unit payment of just $7.66 – below Duggan's estimate of what providers actually paid ($8.15) for this product. The calculation is $9.57 minus Duggan's payment reduction of $1.91 ($9.57 times .19918) = $7.66.

(b) Nebraska: For the first quarter of 1997, Nebraska imposed a MAC of $32.50 for NDC 00074632653 (250 MG Erythromycin tablets) (Ex. 104, Nebraska MAC list at 11.) Duggan applied his composite "difference ratio" derived from his 15-state sample to the total expenditures made by Nebraska to arrive at a dollar value "difference." For the NDC-quarter (00074632653, Q1, 1997), Duggan applies a difference ratio of 20.727%. (3/27/09 Duggan Electronic Production, scbc.dta.) Applying this difference ratio to Nebraska's MAC-based payment for this product ($32.50) would lead to a per-unit payment of just $25.76 – well below Duggan's estimate of what providers actually paid ($27.80) for this product. (3/27/09 Duggan Electronic Production, pricesandunits.dta.) The calculation is $32.50 minus Duggan's payment reduction of $2.04 ($32.50 times .20727) = $25.76. Duggan and Plaintiff thus seem to suggest that, if payment levels were properly set, providers in Nebraska should have taken a 7.3% loss on each prescription of this product to a Medicaid patient. ¶

127. Eleven of the Complaint NDCs were also included in Ven-A-Care's California *qui tam* against Abbott. (*State of California, ex rel. Ven-A-Care v. Abbott Laboratories, Inc., et al*, MDL No. 1456, Original Case No. 03-CV-2238, D. Mass.) (First Complaint in Intervention, Ex. A, Ex. 105.) Because California had a MAIC for many of those NDCs, those claims were dismissed by the Court's March 22, 2007 decision. *See* 478 F. Supp. 2d at 180.

128. On December 9, 2008, a settlement agreement was reached between the State of California, Ven-A-Care and Abbott (as well as other co-defendants) in the case *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc., et al.*, MDL No. 01-12257-PBS (original Case No. 03-CV-2238). (Ex. 106.) The agreement to settle and dismiss claims that Abbott's pricing fraud harmed Medi-Cal even provides that Ven-A-Care "covenant[s] not to sue or take any other civil or administrative action against Abbott based on the Covered Conduct." (*Id*. at ¶ 3.)

129. On September 8, 2008, Abbott reached a settlement with the State of Texas and Ven-A-Care in the case *State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc.*, Case No. D-1-GV-04-01286 (Travis Cty Texas). (Ex. 107.) The Texas settlement agreement provides an identical release. (*Id*. at ¶ 3.)

130. Duggan did not remove claims from California or Texas from his analysis. (4/17/09 Duggan Ery Dep. at 199:22-200:20 ("So if those claims were dropped, if we just whited out the California section, the total difference, I'm sure it would fall.") Ex. 95.)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara A Fumerton, an attorney, hereby certify that I caused a true and correct copy of the foregoing LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS SUPPORTING ABBOTT LABORATORIES INC.'S MOTION FOR SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s Tara A. Fumerton ____
Tara A. Fumerton